IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA, *ex rel.* MARK B. CAMPBELL, STATE OF CALIFORNIA *ex rel.* MARK B. CAMPBELL, STATE OF DELAWARE *ex rel.* MARK B. CAMPELL, STATE OF FLORIDA *ex rel.* MARK B. CAMPBELL, STATE OF GEORGIA *ex rel.* MARK B. CAMPBELL, STATE OF HAWAII *ex rel.* MARK B. CAMPBELL, STATE OF ILLINOIS *ex rel.* MARK B. CAMPBELL, STATE OF INDIANA *ex rel.* MARK B. CAMPBELL, STATE OF LOUISIANA *ex rel.* MARK B. CAMPBELL, STATE OF MASSACHUSETTS *ex rel.* MARK B. CAMPBELL, STATE OF MICHIGAN *ex rel.* MARK B. CAMPBELL, STATE OF MONTANA *ex rel.* MARK B. CAMPBELL, STATE OF NEVADA *ex rel.* MARK B. CAMPBELL, STATE OF NEW HAMPSHIRE *ex rel.* MARK B. CAMPBELL, STATE OF NEW JERSEY *ex rel.* MARK B. CAMPBELL, STATE OF NEW MEXICO *ex rel.* MARK B. CAMPBELL, STATE OF NEW YORK *ex rel.* MARK B. CAMPBELL, STATE OF OKLAHOMA *ex rel.* MARK B. CAMPBELL, STATE OF TENNESSEE *ex rel.* MARK B. CAMPBELL, STATE OF TEXAS *ex rel.* MARK B. CAMPBELL, STATE OF VIRGINIA *ex rel.* MARK B. CAMPBELL, STATE OF WISCONSIN *ex rel.* MARK B. CAMPBELL, and DISTRICT OF COLUMBIA *ex rel.* MARK B. CAMPBELL, **Plaintiffs,** **v.** **WYETH, INC.,** **Defendant.**	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)** **CIVIL ACTION # 07-0051 M** **JURY TRIAL REQUESTED**

FOURTH AMENDED COMPLAINT
(False Claims Act)

PRELIMINARY STATEMENT

1. This lawsuit involves the Defendant's knowing promotion of its kidney transplant drug Rapamune for uses not approved for marketing by the Food & Drug Administration (FDA), in contravention of express warnings on the Rapumune product label that the uses in question had not yet been found to be safe or effective. Wyeth's "off-label" marketing has caused pharmacies throughout the country to submit hundreds of millions of dollars of false claims to the federal Medicare program, the Medicaid program, which is jointly funded by the federal government and individual states, the Federal Employees Health Benefits Program (FEHBP), the Veterans Administration, and the TRICARE and CHAMPUS health care programs of the U.S. Department of Defense. Plaintiff pleads specific information and examples pertaining to four off-label schemes:

a. Between 2003 and approximately July 2006, marketing Rapamune for liver transplant patients after a May 2002 "black box" warning on the FDA-approved product label advised that the safety and efficacy of use for liver transplant patients had not been established;

b. Between 2003 and approximately July 2006, marketing Rapamune for heart, pancreas and other, non-kidney transplant patients after the May 2002 "black box" warning on the FDA-approved product label pointed out the danger of extra-renal use;

c. From July 2004 through the present time, marketing Rapamune for use on a "conversion" basis, i.e., switching a patient over to Rapamune from a different transplant drug, after a warning on the July 2004 FDA-approved label advised that the safety and efficacy of conversion use had not been established;

and,

d. From 2000 through the current time, marketing Rapamune for use in an unapproved combination of immunosuppressive agents, despite the warning on the original FDA-approved package label, and subsequent labels, that the safety and efficacy of Rapamune use in combination with immunosuppressive drugs besides those listed on the label have not been established.

JURISDICTION AND VENUE

2. This is a civil action by Plaintiff Mark B. Campbell, acting on behalf of and in the name of the United States, against Defendant Wyeth, Inc., under the federal False Claims Act (FCA), 31 U.S.C. §§ 3729-3733. This Court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. § 3732(a), which specifically confers jurisdiction on this Court for FCA actions; (ii) pursuant to 28 U.S.C. § 1331, which confers federal subject matter jurisdiction; and (iii) pursuant to 28 U.S.C. § 1345, because the United States is a plaintiff.

3. This court has supplemental jurisdiction over the claims brought on behalf of the state plaintiffs under 28 U.S.C. § 1367.

4. This court has jurisdiction under 31 U.S.C. § 3732(a) over the Defendant because the Defendant can be found in, is authorized to transact business in, and is now transacting business in this District. In addition, acts of the Defendant which are proscribed by 31 U.S.C. § 3729 have occurred in this district, such as Defendant's off-label marketing and the submission of false claims for payment.

5. Venue is proper in this district under 31 U.S.C. § 3732(a), which provides that any action under 31 U.S.C. § 3730 may be brought "in any judicial district in which . . . any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred." Venue is also proper under 28 U.S.C. § 1391.

6. Jurisdiction over all state law claims alleged herein is proper under 31 U.S.C. § 3732(b).

7. None of the allegations set forth in this Complaint is based on a public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, or from the news media.

8. Plaintiff Mark B. Campbell has direct and independent knowledge, within the meaning of 31 U.S.C. § 3730(e) (4) (B), of the information on which the allegations set forth in this Complaint are based. Moreover, prior to filing this lawsuit, Plaintiff Campbell, along with many other Wyeth sales representatives, disclosed to Wyeth management on required reports that Rapamune was being promoted for non FDA-approved uses, including, in particular, use by patients with liver transplants and other organ transplants besides kidney

transplants, and use on a conversion basis, *i.e.*, when a patient, some time after their organ transplant, is switched over to Rapamune from another immunosuppressive regime. Campbell also has provided the key information supporting all of the allegations set forth herein to the United States Department of Justice in a series of presentations, written disclosures, interviews and informal, continuing, updates regarding Wyeth promotional activities. See, *e.g.*, Exhibit A to Second Amended Complaint.

PARTIES

Plaintiff Campbell

9. Plaintiff Mark B. Campbell ("the Relator" or "Campbell") is 48 years old, a citizen of the United States, and a resident of Edmond, Oklahoma. He obtained his Bachelor of Business Administration (BBA) degree from North Texas State in 1984, and then was hired by Wyeth Pharmaceuticals ("Wyeth"), a division of Defendant, Wyeth, Inc., as a sales representative. Campbell worked for Wyeth from March 1986 to August 1989. He resigned from the Company in 1989, giving as his reason his concern that the Company was paying financial inducements to physicians so they would prescribe Wyeth medications. Campbell then pursued and obtained two masters degrees from Southwestern Baptist Theological Seminary, a Master of Arts in Religious Education and a Master of Arts in Marriage and Family Counseling. Campbell was rehired by Wyeth Pharmaceuticals in January 1993 and has worked there through the present time. His current title is Transplant Account Manager for Texas, Oklahoma and Wichita, Kansas. In this position, he markets Wyeth's immunosuppressive product, Rapamune.

Defendant Wyeth, Inc.

10. Defendant Wyeth, Inc., headquartered in Madison, N.J., is one of the world's largest manufacturers of pharmaceutical and other health care products. The Defendant operates in more than 145 countries, employs 47,500 employees worldwide, and had net revenue of $22.4 billion in 2007. Wyeth, Inc. has three major divisions: Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health. This case concerns the conduct of the Wyeth Pharmaceuticals division.

11. Wyeth makes a prescription drug called Rapamune, which is also referred to by the name of its principal ingredient, sirolimus. The drug is an "organ rejection prophylactic" or an immunosuppressive drug, or, in other words, a drug that is designed to prevent the body from rejecting a donor organ that has been transplanted into the body. In 1999, the Food & Drug Administration (FDA) approved the marketing of Rapamune for use in kidney transplant patients as an immunosuppressive drug to be administered to the patient immediately following transplantation. This is called "de novo" use meaning it is prescribed as the first immunosuppressive drug administered to the patient following the kidney transplant.

12. In 1999, the FDA approved the marketing of Rapamune for use in conjunction with only two other immunosuppressive agents: cyclosporine and corticosteroids. In May 2007, the FDA also approved the use of Rapamune in combination with an antibody rejection induction agent.

13. In May 2002, the FDA required Wyeth to include a clear warning inside a separate box on the label - - called a "black box warning" - - informing the public of the serious risks, including graft loss and death, that could result from use of Rapamune by liver transplant patients. In addition, in February 2003, the FDA required Wyeth to include a clear warning inside a separate box on the label - - called a "black box warning" - - informing the public of the serious risks, including death, that could result from use of Rapamune by lung transplant patients.

14. "Conversion" use of Rapamune is when a physician uses a different immunosuppressive agent, which is almost always a calcineurin inhibitor, at the time of transplantation and then switches or "converts" the patient to Rapamune sometime later. The July 2004 FDA-approved label for Rapamune disclosed the results of clinical trials that were uncovering problems with the safety and efficacy of "conversion use." The July 2004 package insert noted for the first time that these problems included "a higher rate of serious adverse events including pneumonia, acute rejection, graft loss and death" in a subset of the patients enrolled in the trials. The language added to the label in July 2004 noted:

> The safety and efficacy of conversion from calcineurin inhibitors to sirolimus [Rapamune] in maintenance renal transplant population has not been established.

15. The FDA has never approved the marketing of Rapamune for use in combination with any other immunosuppressive drug besides cyclosporine and corticosteroids and, in May 2007, an antibody rejection induction agent. The FDA-approved label for the drug contained the following language between 2000 and January 13, 2008:

> In clinical trials, Rapamune has been administered concurrently with corticosteroids and with the following formulations of cyclosporine:
>
> Sandimmune Injection (cyclosporine injection)
> Sandimmune Oral Solution (cyclosporine oral solution)
> Sandimmune Soft Gelatin Capsules (cyclosporine capsules)
>
> Neoral Soft Gelatin Capsules (cyclosporine capsules [MODIFIED])
> Neoral Oral Solution (cyclosporine oral solution [MODIFIED])
>
> The efficacy and safety of the use of Rapamune in combination with other immunosuppressive agents has not been determined.
>
> It is recommended that Rapamune Oral Solution and Tablets be used initially in a regimen with cyclosporine and corticosteroids.

On January 12, 2007, the label was amended to include an additional precautionary warning that the safety and efficacy of de novo use of Rapamune without cyclosporine has not been established in renal transplant patients. This label and all subsequent labels specifically warn that a multicenter clinical study found that de novo use of Rapamune in conjunction with mycophenolate (mofetil) (MMF), also known by the brand name Cellcept ®, steroids and an Il-2 receptor antagonist leads to higher organ rejection and death rates without any improvement in efficacy compared to use of cyclosporine with MMF, steroids and an Il-2 receptor antagonist. This warning continues on the label through the present. The January 14, 2008, label, and subsequent labels retain the recommendation on earlier Rapamune labels that Rapamune should be administered initially in combination with

cyclosporine and corticosteroids, and that cyclosporine should be withdrawn two to four months after transplantation unless the patient has high immunologic risk.

16. Wyeth's Rapamune sales were approximately $364.8 million in 2007. Wyeth's marketing department and senior executives have information indicating that 90% of these sales were for "off label" uses, *i.e.*, uses for which FDA has not approved the marketing of the drug.

17. The Medicare program, the federal-state Medicaid program, FEHBP, the Veterans Administration, and the TRICARE and CHAMPUS health care programs pay for a significant portion of Rapamune prescriptions.

18. Between 1999 and approximately November 2006, Wyeth promoted Rapamune using a sales force of approximately 30 individuals. These Wyeth sales representatives promoted the product by visiting physicians in their offices and urging them to prescribe Rapamune for their patients, by distributing sales literature to physicians, by arranging for doctors to conduct "Investigator Originated Protocols" or, in other words, studies of experimental uses of the drug, and, by inviting physicians to dinners and other gatherings to hear presentations on Rapamune by other physicians paid by Wyeth to speak about Rapamune. Following a reduction in the size of its sales force in late 2006, and continuing through the current time, Wyeth has promoted Rapamune using a sales force of approximately 16 individuals.

Government Plaintiffs

19. The United States of America, the District of Columbia and the states of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Tennessee, Texas, Virginia and Wisconsin, are the plaintiffs for whom recovery is sought for damages to the Medicare program, the federal-state Medicaid programs, FEHBP, the Veterans Administration, and the TRICARE and CHAMPUS health care programs.

FDA REGULATION OF DRUG MARKETING

20. The FDA has the authority to approve the marketing of a drug only for uses that the FDA has found to be both safe and efficacious through clinical trials or otherwise. 21 U.S.C. § 355(d). Drug manufacturers are prohibited from commercially marketing or promoting drugs for non-FDA-approved indications. 21 U.S.C. § 331; 21 C.F.R. § 312.7.

GOVERNMENT HEALTH PROGRAMS' RULES DENYING COVERAGE FOR OFF-LABEL USES

Medicare

21. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, establishes the Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program. The Medicare program is comprised of two parts. Part A provides basic insurance for the costs of hospitalization and post-hospitalization care. 42 U.S.C. §§ 1395c-1395i-2 (1992). Part B is a federally subsidized, voluntary insurance program that pays for a wide range of medical services and supplies, such as physician services. 42 U.S.C. §§ 1395k,

1395l, 1395x(s). Reimbursement for Medicare claims is made by the United States through CMS, formerly known as the Health Care Financing Administration or HCFA (and referred to as "CMS" herein).

22. CMS contracts with private health insurance companies called "carriers" to pay Part B and Part D, Medicare's prescription drug benefit, claims submitted by pharmacies and other providers. 42 U.S.C. § 1395h. In this capacity, the carriers act on behalf of CMS. See 42 C.F.R. §§ 421.100 - 421.128.

23. A person generally is eligible for Medicare coverage if they have End Stage Renal Disease (ESRD), if they are disabled, or if they are 65 years or older. Medicare generally considers an individual undergoing a kidney transplant to be eligible for Medicare benefits based on a diagnosis of ESRD from at least the month of the kidney transplantation through 36 months after transplantation. 42 C.F.R. § 406.13. Pursuant to Section 1881 of the Social Security Act, codified at 42 U.S.C. § 1395rr, Medicare covers the same health care needs for individuals with End Stage Renal Disease as it provides for those who are 65 years or older, or disabled.

24. For those persons eligible for Medicare coverage based on an ESRD diagnosis, Medicare Part B will pay for the "reasonable and necessary" use of certain immunosuppressive drugs following organ transplants covered by Medicare. 42 U.S.C. § 1395y(a); 42 C.F.R. § 410.10; 42 C.F.R. § 411.15(k); Medicare Benefit Policy Manual, Pub. 100-02, Ch. 16, § 20. In general, Medicare Part B may cover an immunosuppressive drug only when it has been approved by the FDA for marketing as an immunosuppressive

therapy specifically to prevent or treat rejection of a transplanted organ, 42 C.F.R. § 410.30, provided certain additional conditions for coverage are met. Rapamune has been approved by the FDA for marketing as an immunosuppressive therapy to prevent or treat rejection of a transplanted kidney in certain circumstances.

25. For those persons eligible for Medicare coverage based on ESRD, age or disability, and enrolled in Medicare Part D, Medicare's prescription drug benefit, Medicare Part D also will pay for the use of immunosuppressive drugs, such as Rapamune, provided certain additional conditions for coverage are met.

26. Even when an immunosuppressive drug such as Rapamune meets the criteria in 42 C.F.R. § 410.30 applicable to Part B coverage, or is a prescription drug covered under Medicare Part D, Medicare will only cover a particular use of that drug if the particular use is also "reasonable and necessary" in the circumstances. 42 U.S.C. § 1395y(a); 42 C.F.R. § 411.15(k); Medicare Benefit Policy Manual, Pub. 100-02, Ch. 16, § 20. To determine that a drug use is "reasonable and necessary," Medicare must first find that the use is "safe and effective." Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15, § 50.4.1. Medicare considers an immunosuppressive drug use to be "safe and effective" when the use is within the scope of the indications specified on the FDA-approved label. *Id.*

27. Claims for immunosuppressive drugs, such as Rapamune, are submitted to Medicare carriers by pharmacies and other providers that fill prescriptions issued by physicians who are treating patients who have undergone organ transplants. Medicare pays for a significant portion of the immunosuppressive therapy administered after organ

transplantation in the United States.

Medicaid - Federal Rule

28. The United States of America, acting through the Centers for Medicare and Medicaid Services ("CMS") and the Health Resources & Services Administration, both of the U.S. Department of Health & Human Services (HHS), funds and oversees the joint federal-state funded Medicaid Program (Title XIX of the Social Security Act, 42 U.S.C. §1396 *et seq.*). The state plaintiffs herein all participate in the Medicaid programs, under which they pay for use of pharmaceutical drugs, including immunosuppressants such as Rapamune, in certain circumstances and for certain indigent individuals who are beneficiaries of such programs. 42 U.S.C. § 1396r-8(d).

29. Federal law defines the prescription drugs that are "covered" by Medicaid to exclude any drug that is "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). Federal law then defines the term "medically accepted indication" to mean "a use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)" which currently include the American Hospital Formulary Service Drug Information; the United States Pharmacopeia Drug Information (or its successor publications) and the DRUGDEX Information System. 42 U.S.C. § 1396r-8 (k)(6). In light of this federal coverage rule, each state Medicaid program may exclude a drug use from Medicaid coverage once it determines that the drug use is not "medically accepted."

42 U.S.C. § 1396r-8(d)(1)(B).

Medicaid - State Rules

30. Many state Medicaid programs have enacted restrictions on coverage of off-label use of prescription drugs. Some of these rules are more stringent or more detailed than the federal rule cited in the preceding paragraph.

31. In the State of California, the Medicaid program ("Medi-Cal") will pay for the use of a drug for a clinical indication not listed in the approved labeling by the FDA only if prior authorization is obtained based on a conclusion by Medi-Cal that the "requested unlabeled use represents reasonable and current prescribing practice." *Manual of Criteria for Medi-Cal Authorization*, Ch. 10-1, IV (rev. April 15, 2004) (available at: http://www.shcs.ca.gov/services/medi-cal/Documents/ManCriteria_30_DrgSuppl.htm).

32. Without specific, written authorization from the Division of Medicaid and Medical Assistance of Delaware's Department of Health & Human Services, the State of Delaware's Medicaid will not pay for a prescription medication unless it is prescribed for an indication that either has been approved by the FDA, incorporated in national standards or "shown to demonstrate both efficacy and safety in a minimum of two peer reviewed journals." *Delaware Pharmacy Provider Manual* (as updated Jan. 8, 2009), § 2.1.6, (available at:

http: www.dmap.state.de.us/downloads/manuals/Pharmacy.Provider.Specific.pdf#page=4). Any other prescriptions are considered experimental and therefore not covered. *Id.*

33. The District of Columbia's Medicaid program does not pay for "experimental

procedures." Washington, D.C., Medical Assistance Administration, *Provider Billing Manual, Physicians*, § 2.5 (Oct. 2006) (available at: http://dchealth.dc.gov/doh/frames.asp?doc=/doh/lib/doh/services/medicaid/pdf/oposrv/new_physicians_billing_manual_062004.pdf).

34. In the State of Connecticut, the Medicaid program does not cover "[a]nything of an unproven, experimental or research nature." Regs., Conn. State Agencies § 17-134d-81(3) (2009).

35. Pursuant to the *Florida Medicaid Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook* (June 2006 ed.) ("Florida Drug Services Handbook") (available at http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/RH_08_080501_Prescribed_Drug_ver1.2.pdf), the State of Florida's Medicaid Program will not cover experimental drugs, and will not cover a drug unless it is "prescribed for medically accepted indications and dosages found in the drug labeling or in drug compendia in accordance with § 1927(k)(6) of the Social Security Act." *Id.* at 2-2 and 2-20. The provisions of the Florida Drug Services Handbook are incorporated by reference in Florida's Administrative Code. Fla. Admin. Code § 59G-4.250 (2008 ed.).

36. In the State of Georgia, the Medicaid program excludes from coverage "agents prescribed for any indication that is not medically accepted." Georgia Dept. of Community Health, Division of Medical Assistance, *Pharmacy Services Manual*, Par. 901.1 (Jan. 1, 2009) (available at https://www.ghp.georgia.gov/wps/portal).

37. In the State of Hawaii, the Medicaid Program only pays for drugs when, *inter alia*, "[t]he drug has been approved by the U.S. Food & Drug Administration for the purpose

for which it is prescribed." WCHR 17-1737-71 (2009).

38. Idaho State requires prior authorization before the state Medicaid program will cover "[m]edications prescribed outside of the Food and Drug Administration approved indications." IDAPA 16.03.09.663.01(h) (2008).

39. The State of Illinois's Medicaid Program covers pharmacy items only when those items are "essential for the accepted medical treatment of a client's presenting symptoms and diagnosis." Illinois Department of Public Aid, *Medical Assistance Program – Handbook for Physicians*, at II-A-21, § A-221.1 (May 2003 ed.) (available at: http://www.hfs.illinois.gov/assets/101006_physician.pdf).

40. The State of Indiana's Medicaid program covers drugs only when they are "approved by the United Stated Food and Drug Administration." 405 Ind. Admin. Code § 5-24-3(a)(1) (2008 ed.).

41. In the State of Iowa, the Medicaid program will not pay for "drugs whose prescribed use is not for a medically accepted indication as defined by Section 1927(k)(6) of the Social Security Act [42 U.S.C. § 1396r-k(6)]." 441 IAC 78.2(249A)(b) (2009).

42. The State of Louisiana's Medicaid Program covers prescription medications only when, *inter alia*, they are "prescribed for medically accepted indicated and dosages found in the drug labeling or in drug compendia, *i.e.*, USP-Drug Information, AMA Drug Evaluations, AHFS-Drug Information System and peer reviewed literature." *Louisiana Medicaid Provider Manual*, Ch. 37, Section 37.5.1 (05/01/06) (available at: http://www.lamedicaid.com/provweb1/manual/FINAL%20PHARMACY%20MANUAL%2012_01_2005.pdf).

43. The State of Maine's Medicaid program does not cover drugs "for experimental use" or for non-FDA approved indications. Maine Department of Health & Human Services, *MaineCare Benefits Manual*, Ch. II, § 80.6(I) (last updated 09/29/07) (available at: http://www.maine.gov/sos/cec/rules/10/ch101.htm).

44. The State of Massachusetts' Medicaid Program "does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence." 131 C.M.R. 406.413 (2008).

45. The State of Maryland's Medicaid program does not cover "[e]xperimental or investigational" drugs. COMAR 10.09.03.05(A)(6) (2009).

46. The State of Michigan's Medicaid program does not cover drugs that are excluded from coverage by Medicare Part D, such as drugs that are prescribed for uses that are neither approved by the FDA nor supported by a reference in the compendia set forth in § 1927(k)(6) of the Social Security Act. Michigan Department of Health, *Medicaid Provider Manual – Pharmacy* at 12-13, § 6 (Jan. 1, 2009) (available at: http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf).

47. Medicaid in the State of Mississippi excludes from coverage drugs that are "still in clinical trials and/or investigative or experimental in nature." CMSR 13-000-011, *Provider Policy Manual*, § 2.03(22) (06/01/07). In addition, to be on Mississippi's preferred drug list and paid for by Medicaid, a drug must be "prescribed and dispensed in accordance with medically accepted indications for uses and dosages." *Id.*, § 31.24 (12/01/06).

48. The State of Missouri's Medicaid program does not cover any "drug or biological used for a medical indication which is not a medically accepted indication." 13 CSR 70-20.030(1) (2008).

49. In the State of Montana, Medicaid will not cover a prescription drug if it is prescribed for "an indication which is not medically accepted as determined by the Department in consultation with federal guidelines, DUE CARE, or the Department medical and pharmacy consultants." Montana Department of Public Health and Human Services, *Prescription Drug Program Manual,* § 2.2 (Nov 2004) (available at: http://medicaidprovider.hhs.mt.gov/pdf/pharmacy.pdf).

50. The State of Nebraska's Medicaid program does not cover medical services when " [t]here is no Food and Drug Administration (FDA) or other governmental/regulatory approval given, when appropriate, for general marketing to the public for the proposed use." Nebraska Admin. Code Title 471, Ch. 1 (2009).

51. The Medicaid program of the State of Nevada reimburses only "covered outpatient drugs" that are prescribed "for a medically accepted indication," and does not cover "experimental" uses of drugs. Nevada Department of Health & Human Services, Division of Health Care Financing and Policy. *Nevada Medicaid Services Manual*, § 1203 at 2-3, § 1203.1A (Dec. 20, 2007 ed.) (available at: http://dhcfp.state.nv.us/MSM%20Table%20of%20Contents.htm?Accept). Nevada defines "experimental" uses to mean uses that are neither approved by the FDA nor supported by the following compendia: American Hospital Formulary Service Drug Information, the U.S.

Pharmacopeia, DRUGDEX or the American Medical Association Drug Evaluations. *Id.*, § 1202 at 2, § 1202.9.

52. The State of New Hampshire's Medicaid Program pays for legend medications only when, among other things, they are prescribed for "use specified by the FDA," or for "non-experimental purposes, as supported by accepted medical practice." N.H. Admin. Rules, He-W 570.04 (2009).

53. The State of New Jersey's Medicaid program does not pay for prescription drugs unless they are "for medically accepted indications as defined in Section 1927(k)(6) of the Social Security Act." N.J.A.C. 10:51-1.13(a) (2009). Section 1927(k)(6) of the Social Security Act, in turn, defines a "medically accepted indication" as "any use for a covered outpatient drug which is approved under the Federal Food, Drug & Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia" listed in a different provision of the Social Security Act, which currently include the American Hospital Formulary Service Drug Information; the United States Pharmacopeia Drug Information (or its successor publications) and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(k)(6).

54. The State of New Mexico's Medicaid Program does not pay for procedures, technologies or therapies considered "experimental or investigational." New Mexico Human Services Department, Medical Assistance Division, *Program Policy Manual,* § 8.301.3.17 (effective 3/1/06) (available at: http://www.hsd.state.nm.us/mad/pdf_files/provmanl/prov83013.pdf). New Mexico considers

a prescription drug use to be "experimental or investigational" if there is no FDA approval of the use, if "further studies or clinical trials are necessary to determine benefits, safety, efficacy and risks" of the use, or if the use "is the subject of ongoing phase I, II or III clinical trials or under study to determine safety, efficacy, maximum tolerated dose and/or treatment." *Id.* § 8.325.6.12 (effective 6/1/03).

55. The Medicaid program of the State of New York does not reimburse for pharmaceutical drugs that do not "meet professionally recognized standards of care." 18 N.Y.C.R.R. 515.2(b)(12)(2009).

56. In North Carolina, Medicaid funds may not be used to reimburse the cost of prescription drugs that the Food and Drug Administration has designated as not having been shown to be effective. 10A N.C.A.C. 2002.0407 (2008). In addition, North Carolina Medicaid does not cover "experimental" medical services. 10A N.C.A.C. 2002.0301 (2008).

57. North Dakota Medicaid does not cover medical services that are "investigational, experimental or unproven"; nor does it cover medical services that are not "appropriate according to generally accepted standards of medical practice." N.D. Admin. Code 75-02-02-08 (2008) and N.D. Admin. Code 75-02-02-03.2 (2008).

58. The State of Ohio's Medicaid Program excludes from coverage "[d]rugs being used for indications not approved by the food and drug administration unless there is compelling clinical evidence to support the experimental use." OAC Ann. 5101:3-9-03(B)(6) (2009).

59. The State of Oklahoma funds prescription drugs under its Medicaid program

only when the FDA has approved and designated the drug as safe and effective. 56 Okl. Stat. § 204.

60. The State of Oregon excludes from Medicaid coverage services or items that are "[c]onsidered experimental or investigational, including clinical trials and demonstration projects, or which deviate from acceptable and customary standards of medical practice or for which there is insufficient outcome data to indicate efficacy." Or. Admin. R. 410-120-1200(2)(j) (2009).

61. In the State of Pennsylvania, Medicaid does not pay for "[d]rugs and devices not approved by the FDA or whose use is not approved by the FDA." 55 Pa. Code § 1121.54(8) (2009).

62. South Carolina's Medicaid program excludes from coverage "investigational pharmaceutical or products." South Carolina Dept. of Health & Human Services, *Pharmacy Services Provider Manual*, updated 03/01/09, (available at: http://www.dhhs.state.sc.us/internet/pdf/manuals/pharm/SECTION%202.pdf).

63. South Dakota's Medicaid program will only cover services that are "medically necessary," which the State defines as services that are, *inter alia*, "recognized as the prevailing standard" and "consistent with generally accepted professional medical standards of the provider's peer group." ASRD 67:16:01:06 .02 (2008).

64. The Medicaid program of the State of Tennessee, called TennCare, only pays for medically necessary services and items. Tenn. Code § 71-5-144(a) (2008). TennCare will not consider a drug to be "medically necessary" if it is "experimental," a term that

Tennesee law defines to include any drug that is not approved by the FDA "unless the use can be shown to be widespread, to be generally accepted by the professional medical community as an effective and proven treatment in the setting and for the condition for which it is used, and to satisfy the requirements of b-1-b-3 [which provide that a service or item is only covered if it is safe and effective, required and the least costly comparable alternative]." Tenn. Code § 71-5-144(b)(4) (2008).

65. The Medicaid program of the State of Texas covers and reimburses "only those drugs listed in the latest edition of the Texas Drug Code Index." 1 Tex. Admin. Code § 3 54.1831(a)(2008).

66. In Utah state, Medicaid does not cover "experimental, investigational or unproven medical practices" or services that have not been "proven to be medically efficacious" for the condition specified. U.A.C. R414-1A-3(1) and (2) (2009). Utah's regulations define the term "medically efficacious" to mean a medical practice that "has been determined effective and is widely utilized as a standard medical practice for specific conditions." U.A.C. R414-1A-2(2)(B) (2009).

67. The State of Vermont's Medicaid program pays for items only if they are "medically necessary," which is defined to mean, *inter alia*, care that is "consistent with generally accepted practice parameters as recognized by health care providers in the same or similar specialty as typically treat or manage the diagnosis or condition." Vermont Agency of Human Services, Office of Vermont Health Access, *Provider Manual*, p.15, rev. 3/2009 (available at: http://ovha.vermont.gov/for-providers/provider-manual-march-2009.pdf).

68. The State of Washington's Medicaid program does not cover drugs that are not approved by the FDA; it also does not cover drugs "prescribed for nonmedically accepted indication, including diagnosis, dose or dosage schedule that is not evidence-based." WAS § 388.530-2100(1) (2008).

69. In the State of Wyoming, to obtain Medicaid coverage of a brand name drug, such as Rapamune, a physician must certify that the drug is "medically necessary," a term that Wyoming's Medicaid regulations define to mean a practice that is "[r]ecognized as the prevailing standard or current practice among the provider's peer group." WCWR 48-130-010, Section 4.rr and Section 6.b.ii. (2008).

FEHBP

70. The federal government provides health care benefits to federal employees through a Federal Employees Health Benefits Program (FEHBP) established under Chapter 89 of Title 5 of the U.S. Code. A FEHBP plan may cover prescription drugs, such as Rapamune. See 5 U.S.C. § 8904(a)(2)(E). Each FEHBP plan contains coverage conditions, many of which are standard conditions of coverage, such as requiring prescribed drugs to be reasonable and necessary for the patient's diagnosis, and/or safe and effective or medically accepted as used.

Veterans' Administration

71. The Department of Veterans Affairs covers prescription drugs for veterans when the drugs are on the VA's National Formulary System, but only when they have been medically determined to be reasonable and necessary for the patient. 38 U.S.C. § 1722A;

38 C.F.R. §§ 17.30 and 17.38. Rapamune (sirolimus) is listed on the VA's National Formulary System.

72. The VA has issued a document entitled "Pharmaceutical Use Outside of Approved Indications/Guidance on 'Off-label' Prescribing" to guide those prescribing medications off-label. The VA requires physicians to be aware of their own prescribing practices, including whether they are prescribing a drug off-label. When a physician unknowingly prescribes a drug off-label, the physician can not determine whether use of the drug is reasonable and necessary. The VA consequently does not cover a drug if a physician unknowingly prescribes it off-label as a result of illegal promotional activity by a pharmaceutical company.

CHAMPUS And TRICARE

73. Through the CHAMPUS and TRICARE Programs, the Department of Defense provides pharmacy benefits for members of the military and their dependents. See 10 U.S.C. § 1071 *et seq.*, 32 C.F.R. §§ 199.17 and 199.21. CHAMPUS covers an off-label use of an immunosuppressive agent only when it is determined to be medically necessary according to accepted standards of medical practice. 32 C.F.R. § 199.4(e)(5)(A)(v). TRICARE will share in the cost of a pharmaceutical drug only when the drug is prescribed "for its labeled indication" unless TRICARE conducts a review and determines based on reliable evidence that the use is both medically necessary and "safe, effective, and in accordance with nationally accepted standards of practice in the medical community." TRICARE Policy Manual 6010.57-M, February 1, 2008, Ch. 8, Section 9.1, Par. 2.2.4 and Par. 2.2.5.

PHARMACEUTICAL SALES PERSONNEL'S CAUSATION OF FEDERAL AND STATE PAYMENT FOR OFF-LABEL PRESCRIPTIONS

74. When a physician evaluates the best treatment regimen for a patient following an organ transplant, the physician ordinarily relies on the representations of the various drug companies, and their sales representatives, concerning the approved indications, risks, and benefits of various organ rejection prophylactic drugs, such as Rapamune. Physicians ordinarily do not have the time to read all of the medical literature, including the often-changing package inserts, for the various immunosuppressive drugs on the market. They must and do rely on the integrity of the pharmaceutical companies and their compliance with FDA regulations regarding promotion.

75. Through their representations to physicians, drug manufacturer sales representatives often cause physicians to prescribe one immunosuppressive drug rather than another for a patient. By issuing the prescription for the marketed drug, the physician, in turn, initiates a chain of events that often leads to the submission of a claim to Medicare, Medicaid, FEHBP, the Veterans Administration or TRICARE or CHAMPUS, by whichever pharmacy ends up filling the physician's prescription.

THE FRAUDULENT ACTIVITIES

Background

76. In 1999, the FDA approved the marketing of Rapamune for "de novo use" after kidney transplantation, *i.e.*, use as the first immunosuppressive drug administered to a patient following a kidney transplant. When the original label was approved, the FDA made clear that it was approving the use of Rapamune in combination with only two other

immunosuppressive drugs: cyclosporine and corticosteroids. In May 2007, the FDA permitted the label to be changed to authorize the marketing of Rapamune for use in conjunction with an antibody rejection induction agent in certain circumstances as well. Through the present, the label recommends that Rapamune should be administered only de novo, and in conjunction only with cyclosporine, corticosteroids and, in certain circumstances, an antibody rejection induction agent. Through January 13, 2008, the FDA-approved label warned that the administration of Rapamune in combination with any other immunosuppressive agents had not been found to be "safe and effective." On January 12, 2007, the FDA required Wyeth to place a stronger and more specific warning on the label stating that the safety and efficacy of de novo use of Rapamune without cyclosporine has not been established, and that a multicenter clinical study has found that the use of Rapamune with MMF (Cellcept) has led to higher organ rejection and death rates without any improvement in efficacy compared to use of cyclosporine with MMF, steroids and an Il-2 receptor antagonist. The latter warning remains on the label through the present day.

77. In subsequent years, in response to the adverse findings of clinical trials and adverse events in medical practice, the FDA required Wyeth to add language to the Rapamune product label to make clear that other uses had not been found to be safe and effective, and were consequently off-label. Thus, in May 2002, the FDA required Wyeth to revise the label to expressly state that Rapamune use in liver transplant patients had not been determined to be safe and effective, and to warn that such use could lead to graft loss or death. This change

served to warn of the dangers inherent in using Rapamune for a non-renal patient without an official clinical trial evaluating the safety and efficacy of the product for that purpose. In February 2003, the FDA required Wyeth to revise the Rapamune label to expressly state that Rapamune use in lung transplant patients had not been found to be safe and effective, and to warn of the serious consequences of such off label use. In July 2004, the FDA further required Wyeth to supplement the product label to state that conversion use had not been found to be safe and effective, and to warn of the serious consequences of converting a patient to Rapamune when he or she was experiencing nephrotoxity or other adverse events from calcineurin inhibitors.

78. As a result of the language on the original label, Wyeth knew from at least September 1999, when the FDA first approved the marketing of Rapamune, that it would violate federal law if it promoted the drug for use in combination with other agents besides cyclosporine and corticosteroids. As a result of the label changes discussed in the preceding paragraph, Defendant also knew from at least after May 2002 that it would violate federal law if it promoted the drug for extra-renal use. Defendant knew from at least after July 2004 that it would violate federal law if it promoted the drug for conversion use. Defendant further understood at all times that Medicare, other federal health insurance programs, and the federal-state Medicaid programs did not cover such off-label uses because such programs only cover treatments affirmatively determined to be safe and effective.

79. Notwithstanding its knowledge of the express statements on its label advising that certain uses of Rapamune have not been found to be safe and effective, and of the

coverage limitations of Medicare, other federal health insurance programs, and the federal-state Medicaid programs, Wyeth management directed and oversaw the promotion of Rapamune for these off-label uses. Wyeth's managers have initiated these off-label promotional activities through a variety of methods including, but not limited to:

* training its Rapamune sales force on the background information needed to market the drug for the off-label use;

* including literature discussing the off-label use on a Wyeth web site called Wyeth "Promotional Materials Ordering System/Rapamune Item List" that was made available to the sales force;

* providing training to the Rapamune sales force that encouraged discussion of the literature addressing the off-label use during sales calls on physicians;

* sponsoring "Continuing Medical Education" ("CME") and other presentations by physicians who spoke on off-label uses;

* encouraging the Rapamune sales representatives to take the initiative to visit with key transplant center directors to see if they would like particular speakers to come in to speak on off-label topics as part of CME programs;

* encouraging the Rapamune sales force to approach physicians about initiating "Investigator Originated Protocols" or "IOPs" to "study" an off-label use of the drug;

* approving business plans and monthly reports that included plans for off-label marketing, such as calls on non-renal physicians and invitations to physicians to engage in off-label IOPs and CME;

* using the business plans and monthly reports of sales representatives who engaged in active off-label marketing as "models" for other sales representatives; and,

* using Visiting Speaker Bureau programs (VSBs) to which sales representatives invite medical personnel to hear Wyeth-paid physicians speak on off-label uses.

80. Wyeth's off-label promotional activity has been highly successful and a key ingredient of the profits the company has made on Rapamune to date. As of the summer of 2006, Wyeth's internal records indicated that approximately 90% of the drug's $200 million in annual sales were for off-label uses. On April 25, 2008, Campbell's supervisor, Gary Anania, informed a physician that 95% of Wyeth sales of Rapamune were off-label.

Scheme I: Post-May 2002 Marketing for Liver Transplant Patients

81. From 2003 through approximately 2006, Wyeth marketed Rapamune for use by liver transplant patients despite the May 2002 "black box warning" on the package label that advised against using Rapamune in liver transplant patients due to the risk of "graft loss" and even "death."

82. In March 2003 - -almost a full year later after the FDA required Wyeth to include the black box warning on the package label - - Wyeth issued new training materials for its Rapamune sales force that contained extensive training on medical issues relating to liver transplantation. For example, Training Module 1 in the Wyeth binder called "Rapamune Learning System," issued in March 2003, contained a six page lesson on "What diseases lead to transplantation of the liver." Training Module 2 in the same binder contained a thirty page chapter on "Liver Transplantation." In the chapter discussing Liver

Transplantation, Wyeth linked the information it provided on liver transplantation to Rapamune treatment, noting in the margin of the chapter: "Flash Forward/Treatment of acute graft rejections is discussed in detail in the Anti-Rejection Therapy Module." These materials advised sales representatives that many immunosuppressive drugs lead to nephrotoxicity, *i.e.,* poisoning of the kidneys, when used on liver transplant patients. Wyeth instructed its sales representatives elsewhere in these materials that these nephrotoxic complications are avoidable if a doctor prescribes Rapamune.

83. Wyeth refers to its sales representatives as "Transplant Account Managers." In a training binder called "Transplant Account Manager Training," issued in 2003 or later, Wyeth instructed its sales representatives when making sales calls on doctors to rely on a visual aid that criticized a competitor drug's "nephrotoxic effects" (*i.e.*, kidney poisoning effects) in "extra renal transplant patients." The visual aid that Wyeth recommended was "OJO," the company's shorthand phrase for an article by Dr. Akinlolo O. Ojo and several other physicians discussing "Chronic Renal Failure after Transplantation of a *Nonrenal* Organ." (Emphasis added.)

84. Management knew that the sales representatives, pursuant to the Wyeth-delivered training, in fact used the Ojo paper, with its discussion of the need to eliminate nephrotoxicity in nonrenal organ transplants, as a visual aid when making sales calls on doctors.

85. Continuing from 2003 through at least 2005, Wyeth management provided the Transplant Account Managers with a report containing data on non-renal transplants at each

transplant center. This report included a column for liver transplant counts at various transplant centers around the country

86. From 2003 through approximately July 2006, Wyeth provided its sales representatives with promotional material concerning use of Rapamune in liver transplant patients, including, but not limited to the article by Dr. Akinlolo O. Ojo and several other physicians discussing "Chronic Renal Failure after Transplantation of a Nonrenal Organ."

87. In a May 2003 marketing report, Wyeth listed Dr. Jeffrey Crippin of Dallas, Texas, and Dr. Richard Harty of Oklahoma City, Oklahoma, as targets of marketing activity. Both of these physicians are liver transplant specialists.

88. In 2005, former Wyeth Transplant Account Manager Linda Lorch marketed Rapamune to liver transplant surgeons at Hermann Hospital in Houston, Texas.

89. In the summer of 2005, former Wyeth Transplant Account Manager Jon Gobba marketed Rapamune to liver transplant surgeons in his sales territory in Michigan. Gobba was one of the sales representatives chosen by management to train other sales representatives.

90. Management affirmatively approved the off-label marketing of Rapamune for liver use by Ms. Lorch, Mr. Gobba and other sales representatives.

91. In or about December 2004 or January 2005, Wyeth Transplant Account Director Paul S. Hughes and Rapamune National Sales Manager Joe McCafferty reviewed and approved those aspects of Ms. Lorch's Business Plans for 2005 that involved promoting

Rapamune for use in liver transplant patients. At the time, Ms. Lorch was the top ranked Rapamune sales representative.

92. In the summer of 2005, Sam Testa, the Transplant Account Director with oversight of Mr. Gobba, reviewed and approved those aspects of Mr. Gobba's Monthly Reports that involved promoting Rapamune for use in liver transplant patients. Mr. Gobba's supervisors also arranged for Mr. Gobba's monthly reports, which made frequent reference to promotion for liver transplant patients, to be sent out to other Transplant Account Managers as models. In early 2005, Mr. McCafferty had sent an e-mail to all Rapumune sales representatives singling out Relator and Jon Gobba for their "success" in selling Rapamune.

93. Between 2003 and approximately July 2006, Wyeth management continuously urged its Rapamune sales force to market Rapamune through the use of CME programs, which management knew included off-label messages about the use of Rapamune in liver transplant patients aimed at physicians. At an early 2006 meeting in Scottsdale, Arizona, attended by Relator, Wyeth management informed the Rapamune sales force that one of the three most important *sales* initiatives for 2006 was "CME."

94. Wyeth also encouraged sales representatives to market Rapamune off-label for liver transplant patients by identifying and facilitating opportunities for off-label "Investigator Originated Protocols" or "IOPs." For example, in her 2005 management-approved business plan, Linda Lorch identified the following need of Hermann hospital: "IOP Interest on part of . . . liver surgeons."

95. In a conference call during the summer of 2006 with four members of Wyeth's Field Implementation Team for Rapamune Sales, Wyeth Marketing Department employee Laura Benoit noted that approximately 90% of Rapamune sales were coming from off-label prescriptions, indicating that Wyeth maintained statistics on the amount of off-label use generated through its liver transplant patient sales activity.

96. Through one or more internal investigations initiated in 2006, Wyeth's compliance department confirmed internal complaints that Wyeth sales representatives were promoting Rapamune off-label for use in patients with transplants of livers and other organs besides kidneys. Wyeth then fired the following sales representatives for off-label marketing of Rapamune for extra-renal patients: Wyeth Transplant Account Managers Colleen Burgeson (based in Denver, Colorado), Michelle Blazek (based in Lincoln, Nebraska), Tammy Lindsay (based in Los Angeles, California), Mark Morelli (based in San Francisco, California), Steve Roof (based in Atlanta, Georgia) and Tammy Lindsay, who was fired just days following her return from maternity leave. Ms. Lorch had resigned her position previously. Mr. Gobba resigned his position in early 2007. Ostensibly for a different reason, Wyeth also fired all three of the supervisors of the terminated Rapamune sales representatives: Transplant Account Director Leslie Hatch, who had supervised Steve Roof; Sam Testa, who had supervised Michelle Blazek; and, Greg Hansen, who had supervised Coleen Burgeson, Mark Morelli and Tammy Lindsay.

97. On February 12 and 13, 2007, Relator Campbell attended a Transplant Account Managers Plan of Action ("POA") meeting held in Plymouth Meeting, Pennsylvania. The

purpose of this semi-annual meeting was to inform the Rapamune sales force of the upcoming sales and marketing plans for Rapamune. The meeting was attended by a number of senior executives in the Wyeth Pharmaceutical Business Unit, which was responsible for pharmaceutical business affairs, sales and marketing. It was also attended by Wyeth's Rapamune sales team. At the meeting, Wyeth Vice President and Chief Compliance Officer Oliver Alivernini admitted that Wyeth had wrongfully trained Rapamune sales representatives on extra-renal uses, and that Wyeth had improperly authorized them to promote Rapamune for extra-renal uses using the article by Dr. Akinlolo O. Ojo and several other physicians discussing "Chronic Renal Failure after Transplantation of a Nonrenal Organ."

98. With regard to its findings on the off-label promotion of Rapamune for use by liver transplant patients, Wyeth neither disclosed the results of its internal investigation to the Government nor offered to repay Medicare, other federal health insurance programs, and the federal-state Medicaid programs for the off-label sales that had been paid for by such programs.

99. Through its marketing strategies, Wyeth knowingly caused physicians, including, but not limited to, physicians at Hermann Hospital, to issue prescriptions for the use of Rapamune by liver transplant patients - - a use which not only was outside the scope of the FDA's marketing approval, but also had been affirmatively determined to be dangerous to patient life and health. These physicians did not necessarily know that this use was off-label; they relied on Wyeth to promote the drug according to its FDA-approved uses and were

entitled to presume that the FDA had approved Rapamune for use by liver transplant patients if the Wyeth sales representatives were promoting the drug in that fashion.

Scheme II. Post-May 2002 Marketing for Pancreas, Islet, Heart & Lung Patients

100. Even after the FDA in May 2002 required Wyeth to include language on the Rapamune label warning against the use of Rapamune in liver transplant patients to guard against the risk of graft loss or death, Wyeth from 2003 through approximately July 2006 continued to market Rapamune not only for liver transplant patients, but also for other non-renal transplant patients, such as heart, pancreas, islet and lung transplant patients.

101. Wyeth issued new training materials in March 2003 - - almost a full year after the black box warning - - that provided sales representatives with the requisite medical background and a promotional pitch to promote Rapamune for heart transplant patients. In Module 1, these materials included a seven page lesson on "What Diseases lead to transplantation of the heart" and, in Module 2, they included a thirty-five page chapter on "Heart Transplantation." In the chapter discussing Heart Transplantation, Wyeth linked the information it provided on heart transplantation to possible use of Rapamune, noting in the margin of the chapter: "Flash Forward/The use of various immunosuppressive agents is discussed in detail in the module entitled Anti-Rejection Therapy" and "Flash Forward/Treatment of rejection episodes is discussed in the Anti-Rejection Therapy module." These training materials advised sales representatives that many immunosuppressive drugs, when used for heart transplant patients, lead to "nephrotoxic" complications, *i.e.*, poisoning

of the kidneys. Wyeth instructed its sales representatives elsewhere in these training materials that nephrotoxic complications are avoidable if a doctor prescribes Rapamune.

102. In the training binder called "Transplant Account Manager Training," issued in 2003 or later, Wyeth instructed its sales representatives when making sales calls on doctors to use as a "visual aid" to their discussion of Rapamune the article by Dr. Akinlolo O. Ojo and several other physicians discussing "Chronic Renal Failure after Transplantation of a *Nonrenal* Organ." (Emphasis added.) The term non-renal transplant patient of course, includes heart, pancreas, islet and lung transplant patients, as well as liver transplant patients.

103. As late as February 2005, Wyeth management continued to provide the Transplant Account Managers with a report containing data on non-renal transplants at individual transplant centers. This report included columns for pancreas, heart and heart/lung transplant counts at various transplant centers around the country.

104. In a May 2003 marketing report, Wyeth listed heart/lung transplant physician Dr. David Nelson of Oklahoma City, Oklahoma, as a target of marketing activity.

105. In 2005, former Wyeth Transplant Account Manager Linda Lorch marketed Rapamune to the director of pancreas transplants at Hermann Hospital in Houston, Texas, for use by pancreas transplant patients. In addition, she marketed Rapamune to St. Luke's Episcopal Hospital in Houston, Texas, for use by heart transplant patients.

106. In 2007, Dr. Van Buren of Houston, Texas, asked Relator whether Wyeth was still marketing Rapamune for use in islet patients.

107. Donna Duval, a former Wyeth Transplant Account Manager in southern California, paid regular visits to heart transplant centers following the black box warning on use in liver transplant patients. She called upon the heart transplant centers to promote the use of Rapamune by heart transplant patients. During these visits, Ms. Duvall conducted "in-services," which are a type of promotional effort in which the sales representative speaks with many members of the health care facility at the same time in an effort to influence their prescribing practices. In an April 22, 2003 internal Wyeth memorandum, she acknowledged both that she knew that Rapamune was not approved for cardiac transplant patients and that her marketing efforts included visits to cardiologists at Sharp Medical Center and University of California at San Diego. In the memorandum, she also recommended Dr. Judd Hunt to other sales representatives as a speaker on the use of Rapamune in heart transplant patients.

108. In her 2005 management-approved business plan, Linda Lorch identified the following need of Hermann hospital: "IOP [Investigator Originated Protocol] Interest on part of pancreas director." In the "Actions Planned" part of her business plan for Hermann hospital, she noted: "Support investigation of possible pancreas IOP with Richard Knight and MSI." In her 2005 business plan for St. Luke's Episcopal Hospital, in the section called "Suggestions for Account Plan Moving Forward," she noted: "IOP follow-up with MSL and self for the heart protocol – Dr. Radovancevic."

109. Management affirmatively approved the off-label marketing of Rapamune for heart, pancreas and other extra-renal use.

110. In or about January 2005, Wyeth Transplant Account Director Paul S. Hughes and Rapamune National Sales Manager Joe McCafferty reviewed and approved those aspects of Ms. Lorch's Business Plans for 2005 that involved promoting Rapamune for use in pancreas and heart transplant patients.

111. The Transplant Account Directors who supervised Donna Duval reviewed and approved those aspects of Ms. Duval's monthly plans that called for promotional visits on heart transplant centers.

112. In a conference call on May 5, 2006, with four members of Wyeth's Field Implementation Team for Rapamune Sales, Wyeth Marketing Department employee Laura Benoit noted that approximately 90% of Rapamune sales were coming from off-label prescriptions, indicating that Wyeth maintained statistics on the amount of off-label use generated through its extra-renal sales activity.

113. Through one or more internal investigations initiated in 2006, Wyeth's compliance department confirmed internal complaints that Wyeth sales representatives were promoting Rapamune off-label for use in patients not only with transplants of livers, but also with transplants of other non-renal organs. Wyeth fired the sales representatives listed in Paragraph 96 for off-label marketing of Rapamune for extra-renal patients, and fired their supervisors ostensibly for other reasons.

114. With regard to its findings on the promotion of Rapamune for heart, pancreas, islet and lung patients, Wyeth neither disclosed the results of its internal investigation to the Government nor offered to repay Medicare, other federal health insurance programs, and the

federal-state Medicaid programs, for the off-label sales that had been paid for by such programs.

115. Through its marketing strategies, Wyeth knowingly caused physicians such as physicians at Hermann Hospital and St. Luke's Episcopal Hospital in Houston, Texas, to issue prescriptions for the use of Rapamune by patients who had undergone transplants of the heart, pancreas, islet and lung - - uses which not only were outside the scope of the FDA's marketing approval, but, in the case of use following a lung transplant, had been affirmatively determined to be dangerous to patient life and health. These physicians did not necessarily know that these uses were off-label; they relied on Wyeth to promote the drug according to its FDA-approved uses and were entitled to presume that the FDA had approved Rapamune for use by pancreas, heart and lung transplant patients if the Wyeth sales representatives were promoting the drug in that fashion.

Scheme III. Post-July 2004 Marketing for Conversion Use

116. From the time that the product label was changed in July 2004 to expressly state that conversion use had not been found to be safe and effective, Wyeth's management has failed to adequately train or inform Wyeth's sales representatives about the FDA's limited approval of Rapamune for de novo use only.

117. From July 2004 through the present time, Wyeth's management, through field instruction by district management and at national training meetings, and by requesting that TAMs utilize promotional materials with an off-label message, has directed and encouraged Wyeth's Rapamune sales team to market Rapamune for conversion use.

118. Wyeth provided its Zone 2 sales force with promotional information on conversion use that was false and contradicted by Rapamune's own product label. Thus, in a 2006 presentation, Wyeth provided its Zone 2 sales force with a chart on "Early to Late Conversion to Sirolimus and Worsening Proteinuria Predictors." At the bottom of the chart appeared the following statement: "Conclusion: Sirolimus is beneficial in patients with CAN [chronic allograft nephropathy]. Poor response factors are % glomular sclerosis, level of proteinuria and presence of chronic transplant glomerulopathy. Baseline GFR [glomerular filtration rate] is not associated with poor outcome." However, approximately two years earlier, in July 2004, the FDA had required Wyeth to include the following warning on its product label: "enrollment [in clinical trials of conversion] was stopped in the subset of patients (n=90) with a baseline glomerular filtration rate of less than 40 ml/min. There was a higher rate of serious adverse events including pneumonia, acute rejection, graft loss and death in this sirolimus treatment arm." Thus, Wyeth trained Transplant Account Managers contrary to the FDA's warning regarding GFR and its relationship to serious adverse events when patients were converted to Rapamune.

119. Wyeth knew and understood that the Rapamune sales team was marketing the product for conversion use throughout the country. Wyeth sales representatives openly discussed with their management promotion for conversion use, and even submitted reports and business plans to their superiors in which they discussed promoting the product for conversion use. Physicians paid by Wyeth gave presentations to other physicians that

promoted the product for conversion use. Sales materials and medical journals distributed by sales representatives to physicians were used by the sales force to market conversion.

120. For example, in early January 2005, at the request of Joe McCafferty, National Sales Manager for Rapamune, Campbell prepared a PowerPoint presentation about his marketing of Rapamune at a hospital in his territory - - Baylor Medical Center. Before the presentation was delivered, Campbell sent a draft of the presentation to McCafferty for his review and approval. McCafferty approved it. In the presentation, Campbell emphasized a sales strategy that involved marketing Rapamune for use in conversion patients. An element of the strategy outlined on the PowerPoint presentation was to "reach for the 'low hanging fruit' . . . conversions." Campbell made the PowerPoint presentation at a Wyeth national meeting in Miami, Florida, on January 18-19, 2005. The meeting was attended by all Wyeth Transplant Account Managers, marketing personnel, and medical affairs personnel who had any connection to Rapamune. No one said anything in response to the presentation to indicate that Rapamune should not be used for conversion patients. To the contrary, the entire Rapamune sales force received an e-mail from McCafferty immediately following the national meeting which lauded Campbell's success in marketing the drug.

121. Wyeth management affirmatively approved the marketing of Rapamune for conversion use. In a "Business Plan" for Baylor Medical Center, the hospital in his territory that was the subject of his PowerPoint presentation, Campbell reported to his supervisors that "Baylor has begun converting all pts. with existing malignancies to Rapa. They are considering a routine conversion (6-12 months) protocol." At the end of this Business Plan,

which he prepared in the Fall of 2005, Campbell noted that he would like to see Baylor "develop a routine conversion protocol" and indicated that he would achieve this desired change through "frequent calls on key prescribers and monthly in-services for the entire team." In the Plan, he remarked on the following "barriers to acceptance" at Baylor: "apathy, resistance to convert a 'stable patient.'" In particular, he remarked that Dr. Larry Melton, Medical Director of Baylor's Regional Transplant Program, is "hesitant to convert 'stable' pts. due to 'patient objection.'" He further noted that Dr. Nesser, a Baylor Program Director, "is not a strong leader and therefore won't lead the charge for a formal conversion program." On the other hand, he observed that: Dr. Barri "is fairly quick to convert, though he does have some concerns about anemia and lung issues"; Dr. Corpier "[c]onverts to Rapa upon biopsy of CAN, but has significant concerns about anemia," and Dr. Rice "converts rather quickly and would like to see Baylor move toward a routine conversion protocol." Transplant Account Director Scott Hughes and Rapamune Sales Manager Joe McCafferty reviewed and approved Campbell's business plans. Moreover, in 2006, Campbell received a "4" or "Exceeds Expectations" as his annual performance appraisal for his work in 2005. (Wyeth's performance appraisal scale goes from 1 to 5.)

122. Transplant Account Director Hughes and National Rapamune Sales Manager Joe McCafferty reviewed and approved 2005 Business Plans by Wyeth sales representative Linda Lorch that openly discussed her intention of promoting Rapamune for conversion use at: Methodist Hospital in Houston, Texas; Willis-Knighton/LSU Medical School in

Shreveport, Louisiana; St. Luke's Episcopal Hospital in Houston, Texas; and UTMB in Galveston, Texas.

123. In or about 2005 or 2006, Geno Germano, Executive Vice-President & General Manager of Wyeth's Pharmaceutical Unit, and Robert Repella, Senior Vice-President of Sales, in discussions with Transplant Account Director Leslie Hatch approved plans to promote Rapamune for conversion use.

124. Sales for conversion use were also openly discussed by management with the sales representatives as a basis for assessment of their performance. For example, in a March 3, 2005, field activity report, Scott Hughes, a Transplant Account Director who supervised Campbell, states: "there has been no growth in < 7 month i [sic] showing that the center in Okla City are doing the early conversion on those where De Novo use was delayed. However, there has been no other center that has a protocol-driven early conversion prior to 7 months . . . the focus is to continue driving utilization at earller [sic] time points using renal function as the key message." In addition, in a field activity report dated June 1, 2005, Hughes states in his comments on Campbell's performance data: "Sales performance was flat as reported in the Feb. sales reports. Baylor D.N. [de novo] and early conversion showed significant loss over the last six months reporting."

125. Wyeth encouraged its sales force to initiate discussions with transplant directors about CME programs and IOPs involving off-label, conversion use of Rapamune. Directly or through CME grants, Wyeth paid the following physicians who spoke on conversion use: Dr. Osama Gaber; Dr. Francesca Egidi and Dr. Jeremy Chapman. For

example, Wyeth Transplant Account Manager Brad Julian arranged for Dr. Gaber to speak on conversion use of Rapamune at the Baptist Medical Center at Wake Forest University. At Wyeth sponsored CME programs that took place after the July 2004 warning language was added to the package label, Dr. Osama Gaber regularly used a PowerPoint document to discuss the conversion protocol used at the University of Tennessee at Memphis Medical School.

126. In approximately June or July 2006, Wyeth received conclusive information indicating that the FDA in all probability would not be approving Rapamune for a conversion indication. Wyeth management relayed this information to the Rapamune sales team in a conference call on approximately July 11 or 12, 2006. Management stated on the call that clinical trials were exposing problems with using Rapamune in the conversion context. The sales team was *not* told, however, to discontinue marketing the drug for conversion use, and the sales team proceeded to promote the drug for conversion use as they had being doing for the past few years.

127. Less than two weeks later, on July 24, 2006, Wyeth's Vice President for Sales, Robert Repella, sent an e-mail to all members of the Rapamune sales team stating that Wyeth "recently" learned of "possible off-label promotion of Rapamune." Wyeth management now informed the sales force for the first time, via this e-mail, that Rapamune was not approved for a use in which physicians "use a different immunosuppressive agent at the time of transplantation (*i.e.*, de novo) and then switch or convert the patient to Rapamune sometime later . . . this practice is sometimes referred to as conversion." Repella stated in the e-mail

that the conversion use "cannot be promoted by Wyeth and discussing these topics with your customers is inconsistent with Wyeth policy."

128. In a conference call during the summer of 2006 with four members of Wyeth's Field Implementation Team for Rapamune Sales, Wyeth Marketing Department employee Laura Benoit noted that approximately 90% of Rapamune sales were coming from off-label prescriptions, indicating that Wyeth maintained statistics on the amount of off-label use generated through conversion sales activity.

129. In November 2006, Wyeth terminated eight of the 30 members of the Rapamune sales force, including all three Transplant Account Directors who supervised the sales force. In addition, the Company issued "verbal warnings" to 17 of the remaining 22 members, informing the entire group of 17 at the same time that they had illegally promoted Rapamune by marketing the drug for conversion use. Notably, the 17 representatives subject to the verbal warnings were told that this typically would be an offense resulting in termination but that they all were just going to receive "verbal warnings" that would not go in their files. In March 2007, Wyeth also fired Tammy Lindsay, who had earlier been out on maternity leave, for promoting Rapamune for use in heart transplant patients.

130. With regard to its findings on off-label promotion of the conversion use of Rapamune, Wyeth neither disclosed the results of its internal investigation to the Government nor offered to repay Medicare, other federal health insurance programs, and the federal-state Medicaid programs, for the off-label sales that had been paid for by such programs.

131. Beginning in 2007, Wyeth required its sales force to sign detailing certifications acknowledging that they would not promote "unapproved" indications or uses, such as "conversion protocols."

132. Notwithstanding Robert Repella's July 24, 2006, e-mail requesting that the Rapamune sales force discontinue marketing Rapamune for conversion use, and notwithstanding the certifications of compliance with this direction required by Wyeth's Legal Department, members of the Wyeth sales force have continued to market Rapamune for conversion use, and Wyeth management has encouraged and directed the TAMs to engage in this illegal marketing activity. For example, in March 2008, Bob Winters, Wyeth's Executive Director for Transplant Sales, sent a voice-mail to all TAMs lauding two TAMs for achieving a protocol change at the Hershey Medical Center that called for using Rapamune on a conversion basis. The TAMs praised by Winters were Mark Schwab, who reports to TAD Merry Ann Edwards, and Mark Wasko, who reports to TAD Gary Anania. During this same month, TAD Merry Ann Edwards encouraged TAM Jon Alexander to maintain handwritten business plans rather than entering his business plans in the company's computer system. Edwards specifically noted to Alexander that TAM Bill Bankert was hand-writing his actual business plan rather than keeping it on the company's computer system.

133. At the mid-POA meeting on April 8, 2008, Winters delivered opening remarks in which he encouraged the Rapamune sales representatives to initiate protocol changes in their respective territories, and then pointed out that well-known transplant physician

Mathew Weir is "transitioning" one or two patients per week to Rapamune from another immunosuppressive drug.

134. On April 24, 2008, Transplant Account Director (TAD) Gary Anania, who currently supervises Campbell, was questioned by Campbell about Wyeth's marketing goals. In response to questions from Campbell as to whether Wyeth was trying to lead physicians to use Rapamune on a conversion basis, Anania stated to Campbell that if he [Anania] were on the witness stand, he would have to say that Wyeth was indeed leading doctors to conversion, and that Wyeth certainly supports conversion. During this conversation, Anania acknowledged that two medical centers in Campbell's sales territory - - St. Luke's Episcopal Hospital and Hermann Hospital, both in Houston, Texas - - are the only medical centers using Rapamune exclusively on label.

135. On April 25, 2008, Bob Winters sent a voice-mail to the entire Rapamune sales force celebrating the achievements of two sales representatives in garnering protocol changes at their hospitals. One of the lauded achievements was TAM Rebecca Bach's success in getting the University of Kentucky to change its protocol to convert patients from Pro Graf to Rapamune at one month post-transplant.

136. On or about May 1, 2008, Campbell received and was asked to sign another Rapamune Detailing Certification Form that warned, among other things, that "Prohibited Discussions include, but are not limited to, conversation [sic] protocols, RAPAMUNE/tacrolimus combinations, RAPAMUNE/MMF combinations and RAPAMUNE in nonsteroid containing regimens."

137. During the period between October 25 and 28, 2008, Campbell received a final version of a new detail piece, #240154-01, on Rapamune that he had previously seen in draft form. A voice-mail sent to all TAMs in Gary Anania's sales zone several days prior had stated that this detail piece had been approved by the Wyeth compliance department, and that Geno Germano, Vice President, Pharmaceuticals Business Unit, had indicated to Winters that he wanted the new detail piece to be used right away by the sales force in sales calls. This new detail piece advocates "early" use of Rapamune rather than de novo use. The piece states in bright, blue font: "Plan to start early. Planned Early Use Preserved Long Term Renal Function After CsA Withdrawal at 3 Months." To illustrate what was meant by "early" use, the detail piece on page 4 includes a picture of a bar with a blue section on the left that merges seamlessly into a red section on the right, with each of the two colored sections composing about half of the length of the bar. The blue part of the bar is labeled "Early." On page 5 of the detail piece, the red section of the bar reappears with the following language: "Conversion occurred between 6 months and 120 months posttransplant." Since the blue part of the bar, labeled "Early," is immediately adjacent to the red section, with no section in between, the only possible interpretation of the graphic is that Wyeth is telling doctors that conversion use prior to six months post-transplant is approved "early" use.

138. On October 29, 2008, TAM Mark Schwab reported to Campbell that Wyeth's Executive Director for Transplant Sales, Bob Winters, had informed him that, beginning January 1, 2009, TAMs would likely be paid bonuses based on all prescriptions for Rapamune written for the first time within six months after transplantation. In other words,

TAMs would be financially rewarded by Wyeth for successful efforts to market Rapamune for conversion use up to six months post-transplant. In January 2009, Wyeth ultimately informed the TAMs that while 2009 bonuses would not be based on sales after all, 2010 bonuses would be based on sales if Wyeth was able to confirm that its outside sales data vendor could provide accurate data.

139. At a POA1a meeting on November 5 and 6, 2008, in Philadelphia, Pennsylvania, Wyeth management introduced TAMs to the new detail piece. Present at the meeting were: all the TAMs; the two TADs (Gary Anania and Merry Ann Edwards); BobWinters; Iain McGill, Vice President & Global Business Manager, Transplant; Arnout Ploos Van Amstel, Senior Vice President and General Manager, Institutional Business Unit; Ryan Daufenbach, Senior Director, U.S. Rapamune Marketing; Dave Beshel, Marketing Associate, U.S. Rapamune Marketing; Sandi See Tai, M.D., Director, GMM, Transplantation, Clinical Affairs Department. In the November 5th morning session of the POA1a, with everyone present, and prior to the role-playing session that afternoon, TAM Bill Bankert asked Iain McGill (Vice President & Global Business Manager, Transplant), how TAMs can avoid promoting for conversion when they use the new detail piece - Bankert pointed out that the new detail aid leads physicians to the conclusion that conversion in the 316 trial was ineffective only because it was done "too late," and that the aid thereby indicates that physicians should simply convert before six months.

140. At the POA1a meeting discussed in the preceding paragraph, management had scheduled a role-playing session for the afternoon of November 5th, at which TAMs would

practice using the detail piece in sales pitches to each other. When asked previously by management for his input concerning this detail piece and a draft that preceded it, Campbell had raised his concerns that the detail piece would be interpreted by physicians as promotion for conversion use up to six months post-transplant. Before the November 5, 2008, role-playing session, TAD Anania approached Campbell apart from the rest of the group, and then called in Wyeth's Executive Director for Transplant, Bob Winters, and Wyeth's Vice President and Global Business Manager, Iain McGill. Winters told Campbell they wanted his 100% buy-in to the new detail piece before the role-playing session commenced, and Campbell was asked about his views. Campbell stated that he felt comfortable about participating in the role-playing sessions, but wanted to make it perfectly clear that he would use the detail piece only to make a stark comparison between conversion and de novo use. Winters then suggested that Campbell not participate in the role-playing session, an instruction Campbell followed.

141. In the days immediately following the POA1a meeting of November 5 and 6, 2008, Campbell received phone calls from TAMs Jon Alexander and Brad Julian, both of whom called to express concern about Campbell's absence at the role-playing session and to express their agreement with Campbell's concern that the new piece did in fact lead physicians to convert patients to Rapamune in the first six months post transplant.

142. On November 21, 2008, TAD Anania forwarded to Campbell, and other TAMs in the Western Zone, a voice-mail from TAD Merry Ann Edwards, who had just attended a Wyeth-sponsored, Visitors Speaker Bureau program by Dr. Shapiro. In the voice-mail,

Edwards praises Shapiro's presentation, which she describes as "outstanding." Edwards reports in the voice-mail that Dr. Shapiro made the following, off-label pitches in his presentation, among others:

*None of the gold standards in transplant are FDA approved.

*"The thing that you have to do with Rapamune is that when you need to be using Rapamune is before things get bad. By way of analogy, you have a group of people and they're rowing their canoe and they're rowing fast and doing really well and things are going great. But you want them in a different direction because you know that there's a waterfall a mile down the stream. That's what happens in transplants. Things are going well, you're not seeing any change in GFR, but that's the perfect time to be thinking about what you're doing because you want to prevent that damage."

143. In 2008 and 2009, Wyeth managers caused TAMs to mislead physicians during sales calls about the nature of a Wyeth-conducted clinical trial so that physicians would conclude inaccurately that the trial found favorable, clinical results in situations in which patients were converted to Rapamune following transplant. Thus, in a clinical trial referred to within Wyeth as the "310 Rapamune Maintenance Regimen trial," or "310 RMR trial," Wyeth studied the effect of withdrawing cyclosporine use six months post-transplant from the medication regimens of patients who were prescribed Rapamune and cyclosporine as the first immunosuppressant drugs taken post-transplant, i.e. de novo Rapamune patients. The trial found that renal function was preserved with the withdrawal of cyclosporine. Wyeth

managers have instructed TAMs to avoid disclosing to doctors that this trial involved de novo patients. For example, in or about early to mid-March 2009, Anania chastised TAM Pam Ryder for describing this trial as a "de novo" trial in discussions with physicians. In addition, in a March 13, 2009, conference call with the TAMs under his supervision, Anania informed the TAMs that Wyeth was trying to get away from characterizing the trial as a de novo trial; on the call, Anania requested that the TAMs refer to the trial as a "planned early use" trial.

144. Wyeth misled physicians and its sales force when it characterized the 310 RMR trial as a trial of "planned early use" because Wyeth managers use the term "planned early use" interchangeably with the term "conversion" both internally and in discussions with physicians. Thus, Anania instructed Relator on February 2, 2009, to refer to a conversion protocol of Dr. Richard Knight as a "planned early use" protocol. On April 2, 2009, during a sales call also attended by Relator, Anania informed Dr. Richard Mauk of Fort Worth, Texas, that the doctor's proposed conversion of patients to Rapamune three months post-transplant would be "planned early use."

145. In late March 2009, following complaints that Anania and others were marketing the 310 RMR study as a successful trial of conversion use, Winters acknowledged to the Rapamune sales force in a recorded voice-mail message that the 310 RMR trial involved patients using Rapamune de novo and did not involve conversion use. Nonetheless, Winters repeated the instruction that the sales force should characterize the trial to physicians as a "planned early use" trial.

146. Through its marketing strategies from July 2004 through the present time, Wyeth knowingly has caused and is causing physicians, including, but not limited to, Drs. Barri, Corpier and Rice at Baylor Medical Center, transplant physicians at Hershey Medical Center and transplant physicians at the University of Kentucky, to issue prescriptions for the conversion use of Rapamune - - a use which was outside the scope of the FDA's marketing approval. These physicians did not necessarily know that conversion use was off-label; they relied on Wyeth to promote the drug according to its FDA-approved uses and were entitled to presume that the FDA had approved Rapamune for conversion use if the Wyeth sales representatives were promoting the drug in that fashion.

Scheme 4: Marketing Rapamune for Use in Unapproved Combinations of Drugs

147. Rapamune was approved in 1999 for use in conjunction with only two other types of transplant medications: cyclosporine (a calcineurin inhibitor) and corticosteroids. From at least 2000 through April 2007, the FDA-approved drug label stated in unequivocal terms that the use of other immunosuppressive drugs (besides cyclosporine and corticosteroids) in combination with Rapamune has not been found to be safe and effective. Nonetheless, from 2000 through the present time, Wyeth has promoted Rapamune for use in combination with other immunosuppressive agents, including: mycophenolate (mofetil) (MMF), also known by the brand name Cellcept ®; azathioprine; and, tacrolimus, which is also known by its research name (FK or FK-506) and its brand name Prograf. ®.

148. In the "Transplant Account Manager Training" binder, issued in 2003 or later, Wyeth advised the Rapamune sales force that it could promote Rapamune to doctors inclined

to use MMF by pointing out that "[p]reliminary evidence suggests that SRL [sirolimus or Rapamune] in combination with MMF allows for CNI [calcineuron inhibitor, *i.e.*, cyclosporin] elimination with acceptable AR [acute rejection rates]."

149. In the 2003 "Transplant Account Manager Training" binder, Wyeth further directed sales representatives to "[e]ncourage SRL [sirolimus] use as part of triple therapy with MMF/steroids."

150. At a Zone 2 Rapamune sales meeting in Atlanta, Georgia, on March 2, 2006, Wyeth management discussed with Rapamune sales representatives an article that studied the off-label combination of Rapamune, MMF and Prednisone. The article, by T.S. Larson and others, was entitled "Complete Avoidance of Calcineurin Inhibitors in Renal Transplantation: A Randomized Trial Comparing Sirolimus and Tacrolimus." The article was published in 2006 in the American Journal of Transplantation.

151. On an internal Wyeth web site, entitled "Promotional Materials Ordering System/Rapamune Item List," Wyeth made available to its sales representatives for "detailing" (*i.e.*, actively discussing with physicians) several articles that discussed the use of Rapamune in unapproved combinations of drugs. Wyeth sales representatives discussed these articles openly with physicians as part of their marketing efforts. These articles included a 1999 article entitled "Sirolimus (Rapamycin) Based Therapy in Human Renal Transplantation" by Dr. Charles G. Groth, et al. that discussed use of Rapamune in combination with steroids and Azathioprine. The articles also included "De Novo Kidney Transplantation Without Use of Calcineurin Inhibitors Preserves Renal Structure and

Function at Two Years" by Stuart M. Flechner et al., American Journal of Transplantation, 2004, and "The Effect of 2-Gram Versus 1-Gram Concentration Controlled Mycophenolate Mofetil on Renal Transplant Outcomes Using Sirolimus-Based Calcineurin Inhibitor Drug-Free Immunosuppression" by Stuart M. Flechner, et al., Transplantation, April 27, 2005, both of which discussed the use of Rapamune in conjunction with MMF.

152. Wyeth paid for Dr. Stu Flechner to speak in Oklahoma City in December 2002 on the use of Rapamune in combination with MMF.

153. Wyeth paid for Dr. Deepak Mital to speak on combining Rapamune with FK at four separate programs: Wake Forrest University on January 7, 2003; Tucson, Arizona, on May 5, 2003; Loma Linda UMC on May 6, 2003; and, Tulsa, Oklahoma on March 10, 2009.

154. Wyeth paid for Dr. Anthony Langone to speak at the Medical College of George on a treatment regimen involving a combination of Rapamune and MMF that he had used to treat marginal kidney donor ("MKD") recipients and delayed graft function ("DGF").

155. In approximately 2004, Wyeth paid for Dr. Mark Stegall to speak at the Emory Renal Transplant Noon Conference on "Surveillance of Renal Allograft Protocol Biopsies." Dr. Stegall spoke positively on the use of Rapamune in combination with MMF.

156. Wyeth paid for Dr. Osama Gaber to deliver presentations at Baptist Medical Center at Wake Forest University. During a June 28 presentation, according to the notes of the Wyeth sales representative who monitored the talk, Dr. Gaber spoke about an opportunity to change outcomes for End Stage Renal Disease patients by utilizing "powerful non-nephrotoxic agents like Rapa and MMF with powerful induction agents like Thymo."

During a June 29 presentation, also according to the notes of sales representative who attended his talk, Dr. Gaber suggested "that there is no risk level that cannot benefit from RAPA/MMF/STD maintenance therapy with powerful induction therapy."

157. Wyeth paid for Dr. Darla Granger to speak at the University of Minnesota on August 8, 2005, on the topic of "Our Evolving Steroid and Calcineurin Inhibitor Sparing Protocols." In her lecture, Dr. Granger praised the benefits of eliminating cyclosporin and steroids from a post-transplant regimen. She discussed a study that instead combined Rapamune with MMF and basiliximab. Wyeth sales representative Ann O'Keefe wrote up a summary of Dr. Granger's talk, which Wyeth National Sales Manager Joe McCafferty forwarded to the entire Rapamune Sales Force.

158. Wyeth paid for Dr. Stu Flechner to speak to other physicians on "Calcineurin Inhibitor [*i.e.*, cyclosporin] free Immunosuppression in Kidney Transplant: Why?" in Morton's Restaurant, in Dallas, Texas on October 25, 2005. His talk centered on the use of Rapamune in combination with MMF.

159. Wyeth paid for Dr. David Shaffer to speak at Vanderbilt University Hospital on November 16, 2005, on "CNI-free denovo immunosuppression." His talk advocated the use of Rapamune in combination with MMF.

160. In Relator's sales territory, Drs. Freda Levy, Ruben Velez and Pedro Vergne were among the nephrologists who were invited to attend, and did attend Wyeth-sponsored speaker programs concerning off-label use of Rapamune in conjunction with MMF or FK.

161. Using Continuing Medical Education and other speaker programs to drive off-label use of Rapamune in unapproved combinations of drugs has been a key aspect of Wyeth's sales approach. At a Wyeth meeting of the Rapamune sales team within Wyeth Zone Two conducted in Atlanta, Georgia, Joe McCafferty, other managers of the sales force and the Transplant Account Managers discussed the possibility of the following speaker programs: Dr. Mital to speak on the Rapamune/FK combination; Dr. Helderman to speak on the Rapamune/MMF/P combination; and Dr. Gaber to speak on the Rapamune/FK combination. At another Zone meeting of this nature in approximately March 2006 led by Joe McCafferty, management led a discussion of a paper by Dr. Larsen that studied the combination of Rapamune, MMF and Prednisone.

162. As they had been trained to do, Wyeth's sales representatives routinely have approached doctors with suggestions about combining Rapamune (sirolimus) with unapproved immunosuppressive agents such as MMF and FK. Management approved this off-label promotional activity by reviewing and approving proposed business plans prepared by the sales representatives. For example, Wyeth management reviewed and approved the following aspects of Relator's business plans:

* In a Business Plan for Methodist Hospital, under "Objectives": "[g]ain agreement to use Rapa/MMF in select # of patients."

* In the Business Plan for Methodist Hospital, under "Opportunities": "Dr. Brinker's newfound interest in Rapa, particularly Rapa/MMF."

163. Wyeth management has held out as models for other sales representatives those business plans that included off-label marketing initiatives, including marketing Rapamune to be used in unapproved drug combinations by encouraging IOPs of this off-label practice. Thus, in January 2005, when Relator delivered a presentation on his business plan for the Baylor Medical Center account at the Wyeth National Sales Meeting, his PowerPoint slides, which had been cleared with National Sales Manager Joe McCafferty, noted that one of Relator's key account strategies for the Baylor Medical Center was to follow up on the Center's interest in an "Investigator Originated Protocol" or a study to look into the use of Rapamune in combination with MMF.

164. In a conference call during the summer of 2006 with four members of Wyeth's Field Implementation Team for Rapamune Sales, Wyeth Marketing Department employee Laura Benoit noted that approximately 90% of Rapamune sales were coming from off-label prescriptions, indicating that Wyeth maintained statistics on the amount of off-label use generated through its sales of Rapamune for use in combination with immunosuppressive agents other than cyclosporine and corticosteroids.

165. Wyeth knows promoting the combination of sirolimus and MMF, the combination of sirolimus and azathioprine, or the combination of sirolimus and FK-506 constitutes illegal, off-label promotion. After the internal investigation by the compliance department referenced above, Wyeth began requiring sales representatives to sign "detailing certifications" agreeing not to discuss such "unapproved uses" as Rapamune/tacrolimus combinations, Rapamune/MMF combinations or Rapamune in nonsteroid regimes.

166. With regard to its findings on off-label promotion of Rapamune in unapproved combinations of drugs, Wyeth neither disclosed the results of its internal investigation to the Government nor offered to repay Medicare, other federal health insurance programs, or the federal-state Medicaid programs, for the off-label sales that had been paid for by such programs.

167. Notwithstanding Robert Repella's July 24, 2006 e-mail requesting that the Rapamune sales force discontinue marketing Rapamune off-label, and notwithstanding the requirement to sign detailing certifications confirming that Rapamune was not being promoted for use in unapproved combinations, the Wyeth sales force has continued to promote Rapamune for use in unapproved combinations, and Wyeth management has directed and encouraged this illegal activity. For example, on April 25, 2008, Wyeth Executive Director, Transplant Sales Winters sent a voice-mail to the entire Rapamune sales force celebrating the achievements of two sales representatives in garnering protocol changes at their hospitals. One of the lauded achievements was TAM Rebecca Bach's success in getting the University of Kentucky to change its protocol to put patients, one month after transplant, on an unapproved combination of Rapamune plus mycophenolate (mofetil) (MMF) (also known as CellCept). The second lauded achievement was TAM Joe Hunter's success in getting the University of Miami to change its protocol to put patients on an unapproved combination of Rapamune plus tacrolimus (also known by its research names, FK or FK-506, and its brand name Prograf. ®).

168. On June 1, 2008, at a transplant conference in Canada attended by numerous physicians from the United States, Wyeth sales representatives handed out invitations to a Continuing Medical Education event at which Dr. Stuart M. Flechner, who has been a Wyeth-paid consultant and speaker, utilized a PowerPoint presentation discussing the use of Rapamune in combination with mycophenolate (mofetil) (MMF) (also known as CellCept).

169. On March 28, 2009, utilizing the budget of the Rapamune marketing department, which had transferred funds for this purpose to Wyeth's education department, Wyeth sponsored a CME program for health care providers in Dallas, Texas, featuring as speakers Dr. Stuart Flechner and Dr. Mathew Weir. This program falsely informed doctors that combining Rapamune with MMF de novo had been found to be safe and effective, and the program falsely led doctors to believe the FDA had approved the marketing of Rapamune for this purpose. The program brochure expressly stated that "[d]iscussion of unlabeled or unapproved use of any drug . . . will be disclosed to learners." In addition, the brochure stated that the program "does not contain information on commercial products/devices that are unlabeled for use." However, both Dr. Flechner and Dr. Weir presented a plethora of slides containing information on the use of Rapamune with MMF or FK. Moreover, one of Dr. Flechner's conclusory slides affirmatively stated that the use of Rapamune with MMF and steroids had been proven to be safe and effective, a flat contradiction of the warning in the Rapamune product label. Thus, Dr. Flechner's conclusory slide represented as follows:

> CNI-free immunosuppression using antibody induction followed by Sirolimus [Rapamune]-MMF-steroids can be done safely. . . .

> The sirolimus-MMF-steroids combination, which requires therapeutic monitoring, results in better renal function and preserved graft histology for the first few years post-transplant.

At no point do Dr. Flechner's slides or Dr. Weir's slides disclose to the learners at the CME conference that combining Rapamune with MMF or FK is a non-FDA approved, off-label use.

170. Wyeth is responsible for the misleading and false statements of Drs. Flechner and Weir at the March 28, 2009, CME program. Wyeth sponsored the CME program in question. In addition, Wyeth pays Dr. Flechner to serve as a consultant, has hired him to speak for Wyeth's Visitors Speakers Bureau and pays him research and/or grant money. Wyeth makes these payments to Dr. Flechner in exchange for Dr. Flechner delivering a false, off-label message during presentations to other doctors. In addition, Wyeth pays Dr. Weir to serve as a consultant. Wyeth pays these consultant fees to Dr. Weir in exchange for Dr. Weir delivering a false, off-label message during presentations to other physicians.

171. By engaging in the foregoing marketing strategies, Wyeth knowingly has caused physicians such as Dr. Brinker at Methodist Hospital in Dallas, Texas, and transplant physicians at the University of Miami and the University of Kentucky, to issue off-label prescriptions calling for the use of Rapamune in conjunction with MMF, azathioprine, or FK. These physicians did not necessarily know that these uses were off-label; they relied on Wyeth to promote the drug according to its FDA-approved uses and were entitled to presume that the FDA had approved Rapamune for use in combination with MMF, Azathioprine or FK if the Wyeth sales representatives were promoting the drug in that fashion.

Wyeth's Off-Label Promotion Caused Providers to Submit False Claims to Medicare, other Federal Health Insurance Programs, and the Federal-State Medicaid Programs.

172. The overwhelming majority of organ transplants in this country are performed on seniors over age 65 and/or individuals with End Stage Renal Disease – both of which are groups whose health care is covered by Medicare. As a result, a physician prescribing an immunosuppressive drug such as Rapamune will in many cases cause a pharmacy or other health care provider to bill Medicare. The Medicaid, FEHBP, VA and TRICARE/CHAMPUS programs cover a substantial portion of the remaining prescriptions in that they pay for the health care of indigent individuals, federal employees, veterans and U.S. Department of Defense employees.

173. Wyeth, through the foregoing illegal marketing activity, necessarily has caused physicians to prescribe Rapamune for off-label uses, and thereby caused pharmacies and other providers to submit claims to Medicare, Medicaid, FEHBP, the VA and the TRICARE/CHAMPUS programs for uses of immunosuppressive drugs that have not been determined to be safe and efficacious. Since Medicare, other federal health insurance programs, and the federal-state Medicaid programs do not cover uses of drugs in such instances, Wyeth's illegal promotional activity consequently has caused the providers to submit false claims to such programs.

174. Field activity reports indicate that Wyeth has obtained or maintained records pertaining to scripts of Rapamune, and thereby has tracked whether physicians have prescribed the drug de novo or on a conversion basis, and the extent to which the drug has been prescribed in conjunction with MMF, Azathioprine, or FK. Wyeth also has tracked

which prescriptions involve kidney transplant patients, and which involve patients who have received transplants of different organs. Moreover, Wyeth's marketing department has records on the extent to which Rapamune is used for off-label uses. Documents in the control of the Defendant consequently can be used to identify specific false claims to Medicare, other federal health insurance programs, and the federal-state Medicaid programs, and to assess or estimate the dollar value of the false claims to such programs.

Wyeth has Concealed its Off-Label Promotional Activity from the FDA

175. Wyeth has advised its Rapamune sales force to avoid FDA officials at national conventions and to send FDA officials with questions to management for responses. To assist its Rapamune sales force avoid interactions with FDA officials at these conventions, Wyeth has trained them on how to spot FDA officials by looking for name tags showing residences in certain parts of Maryland.

DAMAGES

176. Through the foregoing conduct, Wyeth has caused numerous federal and federal-state health care insurance programs, including Medicare, Medicaid, FEHBP, TRICARE/CHAMPUS and the VA, to pay for prescriptions for Rapamune, MMF and FK that are not covered by those programs because the drug use, or the combination use in question is off-label, unproven, not determined to be safe and efficacious, experimental and/or not supported by prevailing medical standards or references in authoritative medical compendia. The United States and the state plaintiffs have been damaged by hundreds of millions of dollars as a result of Wyeth's wrongful conduct.

COUNT I

(Federal False Claims Act - 31 U.S.C. § 3729(a)(1) and (2))

177. This is a civil action by Plaintiff Mark B. Campbell, acting on behalf of and in the name of the United States, against the Defendant under the False Claims Act.

178. Plaintiff realleges and incorporates by reference paragraphs 1 through 176 as though fully set forth herein.

179. The Defendant knowingly has caused false or fraudulent claims for payment to be submitted to officials of the United States Government, in violation of 31 U.S.C. § 3729(a)(1), and knowingly has made or used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by officials of the United States Government, in violation of 31 U.S.C. § 3729(a)(2).

180. Because of the Defendant's conduct set forth in this Count, the United States has suffered actual damages in the hundreds of millions of dollars, with the exact amount to be determined at trial.

COUNT TWO

(California False Claims Law, Cal. Gov. Code § 12650 *et seq.*)

181. Plaintiff re-alleges Paragraphs 1-176, inclusive.

182. Based on the foregoing allegations, the Defendant is liable under Cal. Gov. Code §12650 *et seq.*

COUNT THREE

(Delaware False Claims and Reporting Act, 6 Del. C. § 1201 *et seq.*)

183. Plaintiff re-alleges Paragraphs 1-176, inclusive.

184. Based on the foregoing allegations, the Defendant is liable under 6 Del. C. § 1201 *et seq.*

COUNT FOUR

(D.C. Procurement Related Claims Act, D.C. Code § 2-308.13 *et seq.*)

185. Plaintiff re-alleges Paragraphs 1-176, inclusive.

186. Based on the foregoing allegations, the Defendant is liable under D.C. Code § 2-308.13 *et seq.*

COUNT FIVE

(Florida False Claims Act, Fla. Stat. §§ 68-081-68.09.)

187. Plaintiff re-alleges Paragraphs 1-176, inclusive.

188. Based on the foregoing allegations, the Defendant is liable under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

COUNT SIX

(Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B)

189. Plaintiff re-alleges Paragraphs 1-176, inclusive.

190. Based on the foregoing allegations, the Defendant is liable under the Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B).

COUNT SEVEN

(Hawaii False Claims Law, HRS § 661-21 *et seq.*)

191. Plaintiff re-alleges Paragraphs 1-176, inclusive.

192. Based on the foregoing allegations, the Defendant is liable under the Hawaii False Claims Law, HRS § 661-21 *et seq.*

COUNT EIGHT

(Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq.*)

193. Plaintiff re-alleges Paragraphs 1-176, inclusive.

194. Based on the foregoing allegations, the Defendant is liable under the Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq.*

COUNT NINE

(Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5.-1 *et seq.* (2005))

195. Plaintiff re-alleges Paragraphs 1-176, inclusive.

196. Based on the foregoing allegations, the Defendant is liable under the Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5-1 *et seq.*

COUNT TEN

(Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq.*)

197. Plaintiff re-alleges Paragraphs 1-176, inclusive.

198. Based on the foregoing allegations, the Defendant is liable under the Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq.*

COUNT ELEVEN

(Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq.*)

199. Plaintiff re-alleges Paragraphs 1-176, inclusive.

200. Based on the foregoing allegations, the Defendant is liable under the Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq.*

COUNT TWELVE

(Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq.*)

201. Plaintiff re-alleges Paragraphs 1-176, inclusive.

202. Based on the foregoing allegations, the Defendant is liable under the Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq.*

COUNT THIRTEEN

(Montana False Claims Act, Mon. Code Anno. § 17-8-401 *et seq.* (2007))

203. Plaintiff re-alleges Paragraphs 1-176, inclusive.

204. Based on the foregoing allegations, the Defendant is liable under the Montana False Claims Act, Mon. Code Anno. § 17-8-401 *et seq.* (2007).

COUNT FOURTEEN

(Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*)

205. Plaintiff re-alleges Paragraphs 1-176, inclusive.

206. Based on the foregoing allegations, the Defendant is liable under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*

COUNT FIFTEEN

(New Hampshire False Claims Act, RSA 167.61(a)-(c) (2009))

207. Plaintiff re-alleges Paragraphs 1-176, inclusive.

208. Based on the foregoing allegations, the Defendant is liable under the New Hampshire False Claims Act, RSA 167.61(a)-(c) (2009).

COUNT SIXTEEN

(New Jersey False Claims Act, NJ Stat. § C2A:32C-1-C2a:32C-17 (2009))

209. Plaintiff re-alleges Paragraphs 1-176, inclusive.

210. Based on the foregoing allegations, the Defendant is liable under the New Jersey False Claims Act, NJ Stat. § C2A:32C-1-C2a:32C-17 (2009).

COUNT SEVENTEEN

(New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (2008))

211. Plaintiff re-alleges Paragraphs 1-176, inclusive.

212. Based on the foregoing allegations, the Defendant is liable under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (2008).

COUNT EIGHTEEN

(New York False Claims Act, NY CLS St. Fin. 187 *et seq.* (2009))

213. Plaintiff re-alleges Paragraphs 1-176, inclusive.

214. Based on the foregoing allegations, the Defendant is liable under the New York False Claims Act, NY CLS St. Fin. 187 *et seq.* (2009).

COUNT NINETEEN

(Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.* (2008))

215. Plaintiff re-alleges Paragraphs 1-176, inclusive.

216. Based on the foregoing allegations, the Defendant is liable under the Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.* (2008).

COUNT TWENTY

(Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185 (2009))

217. Plaintiff re-alleges Paragraphs 1-176, inclusive.

218. Based on the foregoing allegations, the Defendant is liable under the Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185 (2009).

COUNT TWENTY-ONE

(Texas False Claims, Texas Human Resources Code, § 36.002 *et seq.* (2009))

219. Plaintiff re-alleges Paragraphs 1-176, inclusive.

220. Based on the foregoing allegations, the Defendant is liable under the Texas Hum. Res. Code § 36.002 *et seq.* (2009).

COUNT TWENTY-TWO

(Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* (2009))

221. Plaintiff re-alleges Paragraphs 1-176, inclusive.

222. Based on the foregoing allegations, the Defendant is liable under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* (2009).

COUNT TWENTY-THREE

(Wisconsin False Claims for Medical Assistance, Wis. Stat. § 20.931 (2008))

223. Plaintiff re-alleges Paragraphs 1-176, inclusive.

224. Based on the foregoing allegations, the Defendant is liable under the Wisconsin False Claims for Medical Assistance, Wis. Stat. § 20.931 (2008).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Mark B. Campbell prays for the following relief:

1. On Counts One through Twenty-Three, judgment for the United States or the State, as applicable, against the Defendant in an amount equal to three times the damages the federal or state plaintiff government has sustained because of the Defendant's actions, plus a civil penalty of $11,000 for each violation;

2. On Counts One through Twenty-Three, an award to the Relator of the maximum allowed under the federal or state law under which suit is brought by the Relator on behalf of the federal or state plaintiff;

3. Against the Defendant, attorneys' fees, expenses, and costs of suit herein incurred; and

4. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands that this matter be tried before a jury.

Respectfully submitted,

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